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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,935	12/21/2000	Timothy Raymond Hirst	9274	8699

7590 11/18/2003

Mary M Krinsky
79 Trumbull Street
New Haven, CT 06511-3708

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/674,935	Applicant(s) HIRST ET AL.	
	Examiner Khatol S Shahnan-Shah	Art Unit 1645	

-- Th MAILING DATE of this communication app ars on the cov r she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003 and 03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *6-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,8,9*.
4) ☒ Interview Summary (PTO-413) Paper No(s). *14*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's Amendments

1. Acknowledgement is made of Applicants' amendments filed 12/21/2000 paper number 6, which has been entered. Claims 1-23 and 31-35 were amended.

Election/Restrictions

2. Applicants' election with out traverse of May 27, 2003 Paper No. 11 is acknowledged. Applicants elected Group I claims (1-23) which are drawn to a method of stimulating immune response. On a telephonic interview on 10/6/2003 between the examiner and attorney Stephen McNamara (Reg# 32,745) for the election of species the applicants elected species of claims 3 and 5 (Herpes virus) see interview summary paper #14.

3. Currently claims 1-5 are pending. Claims 6-37 are withdrawn from consideration as being drawn to non elected inventions.

4. Claims 1-5 are under consideration.

Information Disclosure Statement

5. Applicants' Information Disclosure Statements, received 8/6/2002, 12/16/2002 and 3/24/2003, papers # 7, 8 and 9 acknowledged.

Abstract

6. This application does not contain an abstract of the disclosure as required by 37 FR 1.72(b). An abstract on a separate sheet is required.

Priority

7. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Priority statement is missing from specification.

A claim for priority under 35 U.S.C. 119 (a) (d) or (f) cannot be based on said application, until proper corrections are made.

Specification

8. The use of the trademarks have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

9. Numerous abbreviations have been noted in the specification without reference to their full names. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for stimulating an immune response to an immunogenic composition against Herpes simplex virus (HSV-1) in mice, does not reasonably provide

enablement for stimulating an immune response to a vaccine against an infectious disease in a mammalian subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 broadly recites the limitation "immune response to a vaccine against an infectious disease in a mammalian subject". This limitation can include any vaccine, against any disease and any mammalian subject including humans. The specification is only enabled for a method for stimulating an immune response to an immunogenic composition against Herpes simplex virus (HSV-1) in mice see examples 1-11.

The instant specification invites the skilled artisan to experiment. The factors, which must be considered in determining undue experimentation are set forth in In re Wands USPQ2d 14000.

The factors include
1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art and the
7) breath of the claims.

With regard to factors one and two cited above the quantity of experimentation needed to determine amounts of the active ingredients, the timetable necessary to achieve efficacious administration, dosage frequency as well as the specific identity of different diseases for which the instant invention is applicable (i.e. will be effective for producing immune response against various infections) there has not been provided adequate guidance in the written description for accomplishing and determining such.

With regard to factors four, five and six, it is noted that there is a great deal of unpredictability

in the treatment of various infectious diseases. The instant specification fails to provide a specific methodological procedure for which the instant method can or is intended to be used for treating various hosts alleged and various infectious diseases and it fails to mention any other specific disease (except herpes virus) or conditions intended for treatment or prevention. The art at the time the invention was made fails to establish predictability with regard to the efficacy of vaccine against various diseases as instantly claimed.

With regard to factors three and seven, it is noted that the working examples are limited to nasal immunization of mice against HSV-1. Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses in vivo efficacy of the instantly claimed vaccines in various alleged hosts and various infectious diseases.

It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicants' alleged discovery, not how to find out how to use it for themselves. see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the immune response" in line 1. There is insufficient antecedent basis for this limitation in the claim.

It is not clear what constitutes the metes and bounds of "an effective amount of an immunomodulator" in claim 1.

Numerous abbreviations have been noted in claim 1 without reference to their full names. Appropriate corrections are required.

It is not clear what applicants intend in recitation of " free from whole toxin" in claims 1 and 2.

It is not clear what applicants intend in recitation of " wherein the infectious disease is one for which the infectious agent is a member of the herpes virus family" in claim 3.

Claims 4 and 5 are indefinite as being dependent from indefinite claim 3.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Holmgren et al. (US 5,681,571).

Claim 1 is drawn to a method for stimulating an immune response to a composition against an infectious disease caused by an infectious agent comprising administering to a subject an effective amount of an immunomodulator containing E.coli heat labile enterotoxin (EtxB) or B subunit of cholera toxin (CtxB).

Holmgren et al. teach a method for stimulating an immune response to a composition against an infectious disease caused by an infectious agent comprising administering to a subject

an effective amount of an immnuomodulator containing E.coli heat labile enterotoxin (EtxB) or B subunit of cholera toxin (CtxB) see claim 1.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same method steps and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clements (US 6,413,523 B1) in view of Marcello et al. (Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 8994-8998, September 1994).

Claims are drawn to a method for stimulating an immune response to a composition against an infectious disease caused by herpes virus comprising administering to a subject an effective amount of an immnuomodulator containing E.coli heat labile enterotoxin (EtxB).

Clements teaches a method for stimulating an immune response to a composition against an infectious disease caused by herpes virus comprising administering to a subject an effective

amount of an immnuomodulator containing E.coli heat labile enterotoxin (EtxB) see abtstract and claims specially claims 1, 9 and 10. Clements does not teach an agent other than EtxB having GM 1 binding activity. However, Marcello et al. teach an agent other than EtxB having GM 1 binding activity (see abstract and left column in page 8995and left column in page 8997). At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the methods taught by Clements and Marcello et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated by the teaching of Clements that E.coli heat labile enterotoxin can be used in combination with an unrelated antigen to achieve a higher immune response (see abstract) to combine EtxB with an agent other than EtxB.

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

November 16, 2003

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER